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K102590

GRIFOLS	TECHNICAL EVALUATION DOCUMENTATION	# Document: TED-FLEBOSET DOUBLE -05

SECTION 5 – 510(k) SUMMARY

DATE OF SUBMISSION: 2010-11-24

SUBMITTER NAME: Laboratorios Grifols, S.A.
SUBMITTER ADDRESS: C/ Can Guasch, 2
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DEVICE TRADE NAME: FLEBOSET DOUBLE
COMMON NAME: I.V. FLUID TRANSFER SETS
CLASSIFICATION NAME: I.V. FLUID TRANSFER SETS (21 CFR 880.5440)

PREDICATE DEVICE(S):

SET GRI-FILL 3.0 6-to-1 (Laboratorios Grifols – K093182)
FLEBOSET MULTIPLE (Laboratorios Grifols – K040456)

DEVICE DESCRIPTION:

Disposable fluid transfer set for connection to a gravity or pump I.V. administration set with drip chamber with luer lock connector or for use with the Gri-fill 3.0 pharmacy compounder.

INTENDED USE:

FLEBOSET DOUBLE is a disposable transfer set through which substances from 2 different vials containing the same solution may be continuously delivered for:

a) IV administration when used in conjunction with a gravity or pump infusion set, with luer-lock connection to the drip chamber, to channel the solution from the source vials to the infusion set, and
b) Pharmacy Compounding when used in conjunction with the Grifill 3.0 pharmacy compounding device and associated transfer sets.

Equipped with a spike on each line and a 0.2 μm hydrophobic air-filter, it minimizes the formation of aerosols when preparing / dispensing the source substances. Facilitates easy puncture of thick rubber stoppers of small diameter. Provides fast fluid addition and extraction due to the large surface area of the air-filter.

Set tubing is PVC with DEHP plasticizer. Do not use with lipids, suspensions or solutions that are incompatible with PVC with DEHP plasticizer. Substances that are known to show incompatibility include, but are not limited to, Paclitaxel, Docetaxel,

Etoposide, Carmustine, Propofol, Nitroglycerin, Isosorbide Dinitrate, Diazepam. For information concerning compatibility of substances, please consult the information provided by the manufacturer.

This device is intended to be used by trained healthcare personnel. It is restricted to sale by or on the order of a physician.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, FLEBOSET DOUBLE is compared with another IV fluid transfer set (FLEBOSET MULTIPLE) and a similar fluid transfer set (SET GRI-FILL 3.0 6 to 1), both previously marketed by Laboratorios Grifols.

Design, features, technological characteristics, mechanical specifications and bench performance of the proposed device have been compared in detail with those of the predicate devices following the guidelines set out in the guidance document "Guidance for Industry and FDA Review Staff – Intravascular Administration Sets. Premarket Notification Submissions [510(k)]".

Fleboset Double is a simpler variation of the Set Gri-fill 3.0 6-to-1 predicate design with very similar indications for use as those of the Fleboset Multiple predicate device. It incorporates small dimension spikes identical to those on the Set Gri-fill 3.0 6-to-1. Fluid transfer tubing material on the new device is identical to the fluid transfer tubing material of both predicate devices. All differences have been addressed in the different bench tests performed on the proposed device.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

Materials, packaging and manufacturing processes used in the proposed FLEBOSET DOUBLE are identical to the predicate device. Previously available chemical, physical, mechanical and biological test data relevant to materials are used to support proposed device biocompatibility and stability as well as some physical and mechanical specifications. Non-clinical bench testing performed on FLEBOSET DOUBLE included leakage testing, infusion flow-rate testing and functional checking as per its intended use. Final evaluation included specific testing for ethylene oxide sterilization process residuals, manufacturing process residuals, sterility and endotoxins on final finished sterilized devices. All tests yielded correct results.

SUMMARY DISCUSSION OF CLINICAL DATA:

No clinical data presented in this submission.

CONCLUSIONS:

We believe the intended use, the indications for use, the functionality and the operation of the FLEBOSET DOUBLE are equivalent to the FLEBOSET MULTIPLE and SET GRI-FILL 3.0 6 to 1. Minor technological differences include simplification of the device configuration (2 spikes / lines instead of 6) and bench-testing confirms that there has been no adverse influence on the safety and performance of the proposed device. Hence, substantial equivalence of FLEBOSET DOUBLE with the legally marketed predicate devices may be established.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Sebastian Gascon
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08150 Parets Del Valles
Barcelona Spain 08150

JAN 13 2011

Re: K102590
Trade/Device Name: FLEBOSET DOUBLE
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: LHI
Dated: December 23, 2010
Received: December 27, 2010

Dear Mr. Gascon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

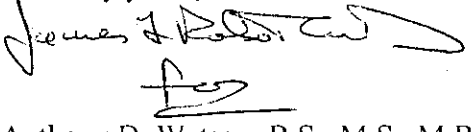
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102590

Device Name: FLEBOSET DOUBLE

Indications For Use:

Disposable transfer set through which substances from 2 different vials containing the same solution may be continuously delivered for:

a) IV administration when used in conjunction with a gravity or pump infusion set, with luer-lock connection to the drip chamber, to channel the solution from the source vials to the infusion set, and

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

1/12/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102590